



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/520,176

01/24/2005

Yuuichi Murayama

101551.55779US

7682

23911 7590 08/01/2008
CROWELL & MORING LLP
INTELLECTUAL PROPERTY GROUP
P.O. BOX 14300
WASHINGTON, DC 20044-4300

EXAMINER

JAVANMARD, SAHAR

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

08/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,176	Applicant(s) MURAYAMA ET AL.	
	Examiner SAHAR JAVANMARD	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 13-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 10/09/2007.

Claim(s) 1-9 and 13-19 are pending. Claim(s) 1-9 and 13-19 have been amended.

Claim(s) 1-9 and 13-19 are examined herein.

Response to Arguments

In view of Applicant's amendments, the 112 1st rejection of claims 13-19 with respect to the term "prevention" is hereby withdrawn.

Applicant's arguments with respect to the 102(b) rejection of claims 1-9, 13-15 and 18 as being anticipated over Richardson et al. (WO 96/21437) has been fully considered and is hereby withdrawn.

Applicant's arguments with respect to the 103(a) rejection of claims 1-9 and 13-19 as being unpatentable over Richardson in view of Gordon (WO 00/64420) has been fully considered but is not persuasive. The rejection is maintained however is modified in the following office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1617

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson in view of Gordon (WO 00/64420).

Richardson teaches a method of remitting or attenuating the symptoms of abnormal movement disorders by administering a meal enriched with large neutral amino acids to patients suffering from these disorders (abstract, page 1, lines 1-3).

Richardson teaches a number of neurological disorders that are manifested by abnormal movements, including among many diseases, Creutzfeldt-Jacob disease (page 2, lines 22-33). Richardson further teaches that branched chain amino acids or aromatic acids are administered to alleviate abnormal movement disorders in particular isoleucine, leucine, and valine (page 10, lines 13-21; page 25, example 2; claims). Additionally, Richardson teaches that the branched amino acids can be administered in the form of various pharmaceutical preparations such as tablets, capsules, flavored bars, suspensions, and emulsions (page 41, lines 11-15).

Richardson does not teach neurodegenerative diseases such as scrapie, bovine spongiform encephalitis, and Gertsmann-Straussler-Scheinker syndrome. Furthermore, Richardson is silent on suppressing the proliferation of abnormal prion proteins.

Gordon teaches that neurodegenerative disease Creutzfeldt-Jakob disease is characterized by the appearance and accumulation of a protein-resistant form of a prion protein in the central nervous system (page 1, lines 25-30) in addition to other neurodegenerative diseases including scrapie, bovine spongiform encephalitis, and Gertsmann-Straussler-Scheinker syndrome (page 23, lines 10-12).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have administered a meal enriched with large neutral amino acids to patients suffering from disorders such as Creutzfeldt-Jacob disease as taught by Richardson as a method for suppressing the proliferation of abnormal prion proteins. One would be motivated to do so because Richardson teaches treating Creutzfeldt-Jacob disease, a disease that, according to Gordon, is characterized by the appearance and accumulation of a protein-resistant form of a prion protein. Thus it would be obvious that by administering to a patient essential amino acids to treat Creutzfeldt-Jacob disease as taught by Richardson, one would also be suppressing the proliferation of prion proteins.

Furthermore, applying the same rationale, one would expect that diseases such as scrapie, bovine spongiform encephalitis, and Gertsmann-Straussler-Scheinker syndrome as taught by Richardson would also be treated by administering a meal enriched with large neutral amino acids to treat the suppression of abnormal protein prion proliferation because all of these neurodegenerative diseases are characterized by the appearance and accumulation of a protein-resistant form of a prion protein in the central nervous system and it is reasonable to treat diseases that have similar characteristics with similar forms of treatment.

Conclusion

Claims 1-9 and 13-19 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617

Application/Control Number: 10/520,176
Art Unit: 1617

Page 6